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NOTICE OF ALLOWANCE AND FEE(S) DUE

27317 7590 1208/2008 Fleit Gibbons Gutman Bongini & Bianco PL 21355 EAST DIXIE HIGHWAY SUITE 115

MIAMI, FL 33180

EXAMINER

STOICA, ELLY GERALD

ART UNIT PAPER NUMBER

1647

DATE MAILED: 12/08/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/559,639	07/24/2006	Dina Ben-Yehuda	7640-X05-046	5095	
TITLE OF INVENTION: LIVIN-DERIVED PEPTIDES, COMPOSITIONS AND USES THEREOF					

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	03/09/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT, PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450

P.O. Box 1450 Alexandria, Virginia 22313-1450 or <u>Fax</u> (571)-273-2885

INSTRICTIONS: This form should be used for transmitting the ISSUE IEEE and PUBLICATION IEEE (required.) Beeks. I through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fee see will be miled to the current correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for unintennance fee notifications.

CURRINT CORRESTORMENCE ADDRESS (Nov. the Book 1 for my chung of address).

Nov. A certificate of mailing on the best of for any other accompanying papers. Each additional papers, such as an assignment of formal derwing, must

	08/2008	have	its own certificate	of mailing or trans	mission.	
Fleit Gibbons Gutman Bongini 21355 EAST DIXIE HIGHWAY SUITE 115	I he Stat addi tran	Certificate of Mailing or Transmission I hereby certify that this Fee(s) Transmital is being deposited with the United States Footal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE: address above, or being faesimile transmitted to the USFIO (271) 272-286S, on the date indicated behavior.				
MIAMI, FL 33180						(Depositor's name)
		_				(Signature)
						(Date)
APPLICATION NO. FILING DAT	Е	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.		CONFIRMATION NO.
10/559,639 07/24/200		Dina Ben-Yehuda		7640-X05-04	46	5095
TITLE OF INVENTION: LIVIN-DERIVED 1	EPTIDES, COMPOSITIO	ONS AND USES THEREOF	4			
APPLN. TYPE SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	FEE TOTAL FE	EE(S) DUE	DATE DUE
nonprovisional NO	\$1510	\$300	\$0	\$1	810	03/09/2009
EXAMINER	ART UNIT	CLASS-SUBCLASS]			
STOICA, ELLY GERALD	1647	530-300000	•			
Change of correspondence address or indication of "Fee Address" (37 ER 1.563). Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. J Fee Address" indication for "Fee Address" indication form PTO/SB/122 indication form PTO/SB/122 or more recent) attached. Use of a Customer Struke of the Address of the Ad						
A. ASSIGNEE NAME AND RESIDENCE DA PLEASE NOTE: Unless an assignee is ide recordation as set forth in 37 CFR 3.11. Co (A) NAME OF ASSIGNEE Please check the appropriate assignee category	ntified below, no assignee mpletion of this form is NO	e data will appear on the p DT a substitute for filing an (B) RESIDENCE: (CTTY	atent. If an assign assignment. and STATE OR C	OUNTRY)		cument has been filed for
la. The following fee(s) are submitted: Issue Fee Publication Fee (No small entity discour Advance Order - # of Copies	tb. Payment of Fee(s): (Plea A check is enclosed. Payment by credit car The Director is hereby overpayment, to Depo	d. Form PTO-2038	is attached.	(s), any defi		
Change in Entity Status (from status indica	atus. See 37 CFR 1.27.	b. Applicant is no lon				
NOTE: The Issue Fee and Publication Fee (if r nterest as shown by the records of the United S	equired) will not be accepte States Patent and Trademar	ed from anyone other than t k Office.	he applicant; a regi	stered attorney or a	gent; or the	assignee or other party in
Authorized Signature			Date			
Typed or printed name						
This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentially is governed by 35 USC 122 and 37 CFR 1.41 his collection is estimated to take 12 minutes to complete, including gathering, preparing, and ubmitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete its form and/or suggestions for reducing this burdon, should be sont to the chief information Office; U.S. Pater and Talendary Office, U.S. Pater a						

OMB 0651-0033

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



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21355 EAST DIXIE HIGHWÄY			ART UNIT	PAPER NUMBER	
SUITE 115 MIAMI, FL 33180			1647		
			DATE MAILED: 12/08/2008		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability

Application No.	Applicant(s)	
10/559,639	BEN-YEHUDA ET A	L.
Examiner	Art Unit	
ELLY-GERALD STOICA	1647	

-- The MALING DATE of this communication appears on the cover sheat with the correspondence address-All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included
herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative
of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- 1. This communication is responsive to 11/25/2008 and 11/26/2008.
- The allowed claim(s) is/are 28-32 and 42-45.
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - - 1. T Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. _____
 - Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDOMMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- 5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) Thereto or 2) to Paper No./Mail Date
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2.
 Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 08/28/2008
- Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date .
- 7. X Examiner's Amendment/Comment
- 8. Examiner's Statement of Reasons for Allowance
- 9. Other _____.

Application/Control Number: 10/559,639 Page 2

Art Unit: 1647

EXAMINER'S AMENDMENT

 An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview that Lorraine Spector and the examiner had with Applicants' representatives, Paul D. Bianco and Katharine Davis Wong, on November 25, 2008. In the interview, Applicant agreed to cancel claim 27 and further to amend some of the claims so as to put them in an allowable condition. Applicant offered to submit a Microsoft Office document containing the agreed upon set of claims which was received by the Examiner on 11/26/2008. The application has been amended as follows:

In the claims all previous sets of claims are to be replaced by the following set:

1-27. (Cancelled)

- 28. (Previously Presented) An isolated or synthetic livin-derived peptide selected from one of p30-Livin α and p28-Livin β , wherein said p30-Livin α peptide comprises the sequence as defined in SEQ ID NO:1 having pro-apoptotic activity, and wherein said p28-Livin β peptide comprises the sequence as defined in SEQ ID NO:2 having pro-apoptotic activity.
- 29. (Previously Presented) An isolated or synthetic peptide as defined in claim 28, wherein said p30-Livin α is denoted by the amino acid sequence as defined in SEQ ID NO:1 and said p28-Livin β is denoted by the amino acid sequence as defined in SEQ ID NO:2.

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Art Unit: 1647

 (Currently Amended) A pharmaceutical composition comprising as active ingredient at least one peptide as defined in claim 28 and a pharmaceutically-

acceptable carrier.

31. (Currently Amended) A pharmaceutical composition as defined in claim 30, for

inducing and/or enhancing apoptosis.

32. (Currently Amended) A pharmaceutical composition as defined in claim 31,

wherein said apoptosis is induced by a treatment or agent selected from the group

consisting of etoposide, anti-CD95/Fas, TNFα and staurosporine.

33. (Cancelled)

34. (Currently Amended) A pharmaceutical composition as defined in claim 31, for

inducing apoptosis in malignant cells.

35-41. (Cancelled)

42. (Previously Presented) A plasmid comprising DNA encoding a p30-Livin α

peptide as defined by SEQ ID NO: 1 or a p28-Livin β peptide as defined by SEQ ID NO:

2.

43. (Previously Presented) A viral vector comprising DNA encoding a p30-Livin α

peptide as defined by SEQ ID NO: 1 or a p28-Livin ß peptide as defined by SEQ ID NO:

2.

44. (New) An isolated or recombinantly-produced livin fragment, said livin fragment

selected from one of p30-Livin α and p28-Livin $\beta,$ said fragment having pro-apoptotic

activity.

Art Unit: 1647

45. (New) A composition comprising as active ingredient at least one livin as defined

in claim 44 and a pharmaceutically-acceptable carrier.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to ELLY-GERALD STOICA whose telephone number is

(571)272-9941. The examiner can normally be reached on 8:30-17:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/

Primary Examiner, Art Unit 1647